

REMARKS

In the Office Action dated December 16, 2002, claim 9 was rejected under §112, second paragraph as being indefinite because the term "said electrophysiology examination set-up protocol" lacked antecedent basis. Claim 9 has been amended to avoid this lack of antecedent basis, and is submitted to be in compliance with §112, second paragraph.

Claims 1-3, 8-10 and 13-15 were rejected under 35 U.S.C. §102(b) as being anticipated by Swenson et al. Claims 4, 5, 6, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swenson et al. in view of Fine et al. Claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Swenson et al. in view of Fine et al., further in view of Fenzlein et al. These rejections are respectfully traversed for the reasons set forth below.

Before discussing the merits of the rejections, Applicant notes that the Examiner included a form paragraph in Section 4 of the Office Action (page 3) stating that the application currently names joint inventors, and reminding the Applicant of the obligations under 37 C.F.R. §1.56 which follow therefrom with regard to the patentability of the claims under 35 U.S.C. §103(a). The present application, however, names only a single inventor, and therefore this form paragraph is inapplicable and should not have been included.

As to the merits of the above rejections, Applicant submits the following arguments in support of the patentability of the claims of the application.

The subject matter disclosed and claimed in the present application is an interface unit (claim 1) and an electrophysiology measurement system (claim 10) wherein a number of mating connections must be made in a particular configuration,

dependent on the nature and type of an electrophysiological study or exam currently being undertaken. As discussed in the introductory portion of the present specification, each type of study or examination has a particular configuration of the mating connections between the sensor leads and the electrical connections leading to the evaluation device. Although various techniques and devices are known in the art for labeling or otherwise designating the appropriate mating configuration at the location where the mating of the leads and sockets take place, none of those known techniques and devices, including those cited by the Examiner provide any type of electrical signal generation which uniquely identifies the particular configuration currently in use, so that the evaluation unit can identify that signal and verify that the correct configuration has actually been made. Even if a label or some other designation on the interface unit itself is employed to provide a visual indication to the person setting up the connections as to the proper connections, there is still the possibility of human error in setting up those connections and/or there is the possibility of a labeling or visual indication being used that is not the correct one for the current examination.

In the subject matter of the present application, as set forth in the dependent claims, different embodiments are possible in association with the aforementioned signal generation. The housing itself may define a unique mating configuration, in which case if the generated signal uniquely identifies the housing, this is the same as designating the unique mating configuration associated therewith. In other embodiments, one or more overlays are provided on the interface unit, each overlay designating a different unique mating configuration. The aforementioned generated

signal in these embodiments then designates the overlay that is currently in place, and thereby also designates the unique mating configuration associated therewith.

No such arrangement is disclosed or suggested in the Swenson et al. reference. The Swenson et al. reference discloses a system for performing electrophysiological measurements, such as ECG measurements, and the system includes an electrophysiology monitoring system 140 and an interface unit 36. The interface unit 36 has a number of electrical contacts 44 for receiving the connection leads of conduit sets 52, used for performing a desired medical examination, as described at column 6, lines 43-61. The Swenson et al. reference also discloses a communication link 48 between the interface unit 36 and preamplifier 26 connected to the monitoring system 140, allowing electrical signals to be communicated from the conduit sets 52 to the monitoring system 140. This is described at column 7, lines 31-40.

In column 3, in the paragraph beginning at line 38, it is stated that the Swenson et al. system includes selecting means that include verifying means for assuring that when the electrical conduits associated with the selected diagnostic test protocol are connected to particular ones of the universal interface contacts, only the pre-selected diagnostic test protocol is enabled for performing on a patient.

This feature in Swenson et al. is described in more detail in column 6. As is clear from that discussion, in the system disclosed in Swenson et al., the interface unit 36 provides only signals to the monitoring system that originate from a patient (i.e., only those signals that arise on the conduit sets 52), as described at column 8, lines 40-46. The intended mating configuration for the interface unit 36 is stored in a storage unit 12 *of the monitoring system 140* and is displayed at a display 20

associated with the monitoring system 140 when a particular test protocol is selected by a user. This is explained at column 6, line 62 through column 7, line 4. Therefore, the monitoring system 140 already "knows" the test protocol that has been selected and the necessary mating configuration therefor, and therefore the interface unit 36 in the Swenson et al. system does not transmit any signal to the monitoring system 140 providing such a designation. The Swenson et al. system therefore operates without a recognition that the most likely location where errors can occur is at the interface unit 36. The interface unit 36 in the Swenson et al. system, therefore, is not intended to provide any signal to the monitoring system 140 of the type set forth in independent claims 1 and 10 of the present application.

Moreover, with regard to claims 4-9, 11 and 12, even though the Swenson et al. system employs labeling to designate particular mating configurations, for the above reasons there is no teaching in the Swenson et al. system to provide a signal from the interface unit to the monitoring system uniquely identifying the particular labeling that is currently being used. If incorrect labeling is present at the interface unit 36 in the Swenson et al. unit, the monitoring system 140 has no way of being informed of this error.

The Swenson et al. reference therefore does not disclose all of the elements of claims 1-3, 8-10 and 13-15 as arranged and operating in those claims, and therefore does not anticipate any of those claims under 35 U.S.C. §102(b).

As to the rejections under 35 U.S.C. §103(a), Applicant submits that either the Fine et al. reference nor the Fenzlein et al. reference provides any teachings or suggestions to generate a signal of the type described above from the interface unit 36 in the Swenson et al. system to the monitoring system 140 in the Swenson et al.

system. Therefore, even if the Examiner is correct as to the teachings of those secondary references as set forth in the Office Action, modification of the Swenson et al. reference in accordance with the teachings of one of both of those secondary references still would not result in an interface unit as set forth in claim 1 nor an electrophysiology measuring system as set forth in claim 10. The dependent claims respectively depending from those independent claims, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Swenson et al. in combination with the teachings of one or both of those secondary references.

All claims of the application are therefore submitted to be patentable over the teachings of the above references, and early reconsideration of the application is respectfully requested.

Submitted by



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claim 1 as follows:

1. (Amended) An interface unit for use with an electrophysiology measurement system having an electrophysiology monitoring system and a plurality of catheter-mounted sensors respectively connected to electrical connectors, said interface unit comprising:

a plurality of externally accessible unit electrical connectors respectively adapted for releasably mating with a one of said sensor electrical connectors in a mating configuration;

an arrangement for producing predetermined interconnections among said unit connectors, said arrangement adapted for communicating with said electrophysiology monitoring system; and

a signal generator connected to said arrangement which emits an output signal, adapted to be received by said electrophysiology monitoring system via said arrangement, containing information unique to and originating from said interface unit and designating said configuration, for use by said electrophysiology monitoring system.

Please amend claim 4 as follows:

4. (Amended) An interface unit as claimed in claim 1 wherein said unit electrical connectors are disposed at an outer surface, and wherein said interface unit further comprises at least one label layer placeable over said outer surface and carrying visible indications of said interconnections to form said configuration, and wherein said signal generator emits said output signal containing information unique to said label layer.

Please amend claim 8 as follows:

8. (Amended) An interface unit as claimed in claim 1 wherein said signal generator generates said output signal containing a protocol for [a] said mating configuration among said sensor and unit connectors.

Please amend claim 9 as follows:

9. (Amended) An interface unit as claimed in claim 1 wherein said signal generator emits said output signal containing at least a portion of [said] an electrophysiology examination set-up protocol.

Please amend claim 10 as follows:

10. (Amended) An electrophysiology measurement system comprising:
a plurality of catheter-mounted sensors respectively having sensor electrical connectors associated therewith;
a monitoring system for analyzing signals from said sensors; and
at least one interface unit connected between said sensors and said monitoring system, said interface unit having a plurality of unit electrical connectors respectively receiving a one of said sensor connectors in a mating configuration and containing an arrangement defining interconnections among said unit connectors, said arrangement being in communication with said monitoring system, and said interface unit further having a signal generator connected to said arrangement for generating an output signal unique to and originating from the interface unit, designating said configuration and being supplied to the monitoring system via said arrangement, said output signal modifying operation of said monitoring system dependent on said information.

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